

REMARKS

By this Reply, claims 25, 35-37, 41, 51-53, 72, and 86 have been amended, claims 101-104 have been added, and claims 56-71 have been canceled. Accordingly, claims 25-55 and 72-104 are pending in this application. No new matter has been added by this Reply.

Applicants would like to thank the examiner for the willingness to grant the personal interview with Applicants' representative on March 23, 2005, and for the courteous responses to the requests from Applicants' representative concerning the status of this application. The arguments presented below are consistent with the positions taken during the personal interview.

In the Office Action mailed on July 5, 2005, claims 25-85 were rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 5,640,977 to Leahy et al. ("Leahy"). In particular, the Office Action states that

Leahy anticipates the claimed invention because of admissions made by Applicant during an interference proceeding, during an Examiner's interview on March 23, 2005 and given that fact that Leahy was declared the winning party of the interference.

(Office Action, page 2.)

The Office Action proceeds to state that the scope of the patented claims of Leahy are so broad that they would "cover" a surgical device and method of providing sealed access through an incision "without the use of adhesive." (Office Action at page 4.) From this, the Office Action states that (1) "the patented claims of Leahy read upon Fig. 9 of the present application and anticipate claims 25-85 of the present application," and (2) that the claims of the present invention are directed to the same patentable

invention lost during the interference. Applicants disagree with these assertions and traverse the outstanding rejection of claims 25-85 for the reasons stated below.

Applicants' Disclosure

Independent apparatus claims 41, 72, and 86 of the present application are directed to a surgical device including, *inter alia*, a distal ring, a tubular diaphragm extending proximally from the distal ring, and an entry seal assembly. Independent claim 25 recites a method of providing sealed access through an incision by way of a device including the same aspects. As shown in Fig. 9 of the present application, such a device can be inserted through an incision in a patient to form a sealed access port for use during a surgical procedure. The surgical device can allow, for example, sealed access to an abdominal cavity that has been insuflated to create a pneumoperitoneum.

As illustrated in Fig. 9 and explained at page 9, line 27, through page 10, line 4, of the present application, the distal ring in association with the tubular diaphragm anchors or seals the device to the patient's body. The distal ring and diaphragm together form the only coupling with the patient's body. By coupling the surgical device to the patient solely by way of the diaphragm and the distal ring the device does not require the use of, for example, an adhesive to maintain the device coupled to the patient during the surgical procedure. This avoids drawbacks associated with adhesive couplings. For example, adhesive couplings are susceptible to separation from the patient resulting in a loss of insuflation pressure from inside the patient. In addition, the adhesive couplings do not utilize the insuflation pressure to assist in coupling the device to the patent. Rather, such adhesive couplings work against the insuflation pressure by tending to separate or detach at increased pressures.

In addition, the coupling of such a device to the body only by a distal ring and tubular diaphragm avoids problems associated with varying thicknesses of patients' skin. The anchoring of the device by the distal ring located within the incision may allow the tubular diaphragm to be stretched or tensioned to extend through many different skin thicknesses.

In contrast, a device that relies on an adhesive coupling to secure the device to a patient outside the body would not necessarily stretch the material extending out from inside the body, and thus would require appropriate sizing to match the thickness of the patient's skin to assure that a distal end of the material does not dangle within the patients body. Accordingly, devices that utilize adhesives to couple the device to a patient outside the body would need to be separately sized for the many different skin thicknesses of patients to avoid excess material from extending into the body.

The Pending Claims are Not Anticipated by Leahy

Addressing the present rejection of claims 25-85 as anticipated by Leahy, Applicants submit that neither the Leahy claims nor the detailed description of Leahy anticipate the claims of the present application. In order to anticipate a claim, every element of the claims must be found either expressly or inherently in a single prior art reference. (M.P.E.P. § 2131.) As will be explained below, Leahy fails to disclose or suggest, every element of pending independent claims 25, 41, 72, and 86, and the claims that depend therefrom.

Leahy discloses a surgical apparatus (10) for permitting hand-assisted laparoscopic surgery. Referring to Figs. 3 and 4 of Leahy, the apparatus (10) includes an outer sleeve (18) having an axial entry opening (23a) and a lateral exit opening (24),

the exit opening being located adjacent an incision in a patient. A first sealing means is provided for sealing the exit opening (24), and a second sealing means is provided for sealing the entry opening (23a). The first sealing means includes an adhesive on a lower exposed flange (26) of the apparatus, the adhesive being adhered directly to the patient's body or to the body by way of a drape (D) that is adhered to the body. (Leahy, col. 3, lines 60-67; col. 5, lines 14, 15; and 31-34; and col. 7, lines 36-43.) The second sealing means may include, for example, an inflatable cuff (20) located at the entry opening (23a). (Leahy, col. 3, lines 49-54.) In addition, Leahy discloses a wound protector 12 separate from the surgical apparatus (10) comprising a thin flexible tube (13) and flexible O-rings (14 and 16) located at opposite ends of the tube (Leahy, col. 2, lines 9 and 10; and col. 4, lines 1-10.)

First addressing independent apparatus claim 41 of the present application, neither the claims of Leahy nor the detailed description of Leahy disclose or suggest a surgical device including, for example, a single patient coupling assembly forming substantially the only coupling between the surgical device and the patient, the single patient coupling assembly including a distal ring and a tubular diaphragm, as required by independent claim 41. With respect to the detailed description of the Leahy patent, the disclosed apparatus requires an adhesive coupling to attach the apparatus to the patient. This adhesive coupling disclosed in the detailed description of Leahy does not comprise a single coupling assembly forming substantially the only coupling and including a distal ring and a tubular diaphragm. Accordingly, the detailed description of Leahy cannot anticipate independent claim 41, or claims 42-55 that depend from claim 41.

Consistent with the scope of the detailed description of Leahy, the claims of Leahy also do not disclose or suggest the claimed single patient coupling assembly forming substantially the only coupling and including a distal ring and a tubular diaphragm recited in independent claim 41.¹ Accordingly, the claims of Leahy also cannot anticipate independent claim 41, or claims 42-55 that depend from claim 41.

Applicants respectfully disagree with the statements in the Office Action that the claims of Leahy “are so broad they also cover a surgical device and method of providing sealed access through an incision without the use of an adhesive” and “[t]herefore the patented claims of Leahy read upon Figure 9 of the present application and anticipate claims 25-85 of the present application.” (Office Action, page 4.) The breadth of the claims of Leahy are not relevant to the issue of whether they anticipate the claims of the present application.

The appropriate test for anticipation is whether the claims of Leahy expressly or inherently include every element of the rejected claims of this application. This type of analysis arises frequently in the context of double patenting rejections where claims of one patent application (or issued patent) are used to reject claims of another patent application. M.P.E.P. § 804 supports the distinction between breadth (or dominance) of claims and anticipation by stating:

Domination and double patenting should not be confused. They are two separate issues. One patent or application "dominates" a second patent or application when the first patent or application has a broad or generic claim which fully

¹ During the relevant interference proceeding between the Bonadio and Leahy, claim 1 of Leahy was identified as the sole count, with claims 1-31 of Leahy indicated as corresponding to the count. Accordingly, discussions in this Reply with respect to the claims of Leahy equally apply to the count identified in the relevant interference proceeding.

encompasses or reads on an invention defined in a narrower or more specific claim in another patent or application.

Domination by itself, i.e., in the absence of statutory or nonstatutory double patenting grounds, cannot support a double patenting rejection.

(emphasis added)

Accordingly, whether or not the claims of Leahy “read upon” or dominate Fig. 9 of the present application, or are in some aspects broader than the claims of the present application, is irrelevant to the anticipation analysis.

Similarly, the comments in the Office Action alleging that statements in the relevant interference proceeding amount to an acknowledgement by the Applicants that the Leahy device “covers the embodiment of Figure 9 of the present application” are also irrelevant to the anticipation analysis. (Office Action, page 5.) Along these same lines, Applicants disagree with the comments in the Office Action alleging that certain statements in the relevant interference proceeding concerning the scope of the claims of Leahy are an acknowledgement that “the claims of Leahy’s device can be used without an adhesive.” (Office Action, pages 4 and 5.) Even assuming the statements made during the relevant interference proceeding were to amount to an admission that the scope of certain claims of Leahy were broad enough to cover the device depicted in Fig. 9 of the present application, such statements would in no way imply that the claims disclose the single patient coupling assembly as recited in independent claim 41 of this application.

In view of the above, Applicants submit that independent claim 41 is not anticipated by either the claims or detailed description of the Leahy patent. Accordingly, Applicants request that the rejection of independent claim 41 be withdrawn.

Additionally, the rejection of claims 42-55 that depend from independent claim 41 should be withdrawn for at least the reasons provided above.

Independent apparatus claim 72 of the present application recites, among other things, a single patient coupling assembly forming substantially the only coupling between the surgical device and the patient, the single patient coupling assembly including a distal ring and a tubular diaphragm. This is the same language discussed above with respect independent claim 41. Accordingly, for at least the same reasons stated above, Applicants submit that independent claim 72 is not anticipated by the claims or detailed description of Leahy. In view of this, Applicants request that the rejection of independent claim 72 be withdrawn, along with the rejection of claims 73-85 that depend from claim 72.

Independent apparatus claim 86 of the present application recites, among other things, a tubular diaphragm extending proximally from the distal ring, the distal ring and diaphragm configured to provide substantially the only seal between the patient incision and the device. This claim language is similar to the claim language discussed above with respect to independent claim 41. Applicants submit that claim 86 and its dependent claims 87-100 are allowable for at least the same reasons discussed above traversing the rejection of independent claim 41.²

Independent method claim 25 of the present application recites a method of providing access through an incision including, among other things, coupling the

² Applicants note that the outstanding Office Action does not include a rejection of claims 86-100. The only reference to these claims is found on the Office Action Summary form included with the Office Action. The Office Action Summary form lists claims 86-100 as pending and rejected. Applicants request a clarification of the status of these claims in the next communication from the Patent Office.

surgical device to the patient solely by inserting the distal ring through the incision such that at least a portion of the diaphragm extends through and engages the incision. This claim language is similar to the claim language discussed above with respect to independent claim 41. For at least the same reasons stated above in connection with independent claim 41, Applicants submit that independent claim 25 is not anticipated by the claims or detailed description of Leahy. Accordingly, Applicants request that the rejection of independent claim 25 be withdrawn, along with the rejection of claims 26-40 that depend from claim 25.

The Pending Claims are Not Estopped Under 37 C.F.R. § 41.127(a)(1)

37 C.F.R. § 41.127(a)(1) states that a losing party to an interference who could have properly moved, but failed to move, shall be estopped to take actions in the Patent Office inconsistent with the failure to properly move. See M.P.E.P § 2363.03. For example, 37 C.F.R. § 41.121 may permit a motion in an interference proceeding to redefine the interfering subject matter by adding or substituting a count. Application of these and other relevant rules to the present case indicates that estoppel will not apply to the claims of the present application if: (1) Leahy could not support the claims of the present application or add such claims, and (2) the claims of the present application are directed to a separate patentable invention from the count. As will be explained in detail below, the claims of the present application are not supported by the disclosure of Leahy, could not be added nonetheless because Leahy was a granted patent, and lastly, define a separate patentable invention over the claims/count of Leahy.

For the same reasons provided above that the claims and detailed description of Leahy do not anticipate the claims of the present application, the claims of the present

application are not supported anywhere by the Leahy disclosure. Accordingly, Applicants could not have moved to add a count to the earlier interference proceeding directed to the invention of the pending claims of this application. And, even assuming *arguendo* the Leahy disclosure did support such claims, Leahy could not be amended during the interference because it was a granted patent.

In addition, the claims of the present application define a separate patentable invention over the count of the interference. A separate patentable invention requires the pending claims to be new (35 U.S.C. § 102) and non-obvious (35 U.S.C. § 103) the count. See 37 C.F.R. 41.203. For at least the reasons stated above, the claims of the present application are new in view of the count and all of the claims of Leahy, including claim 1, which corresponds to the count.

Independent apparatus claim 41 recites a surgical device including, *inter alia*, a distal ring, a tubular diaphragm extending proximally from the distal ring, and a single patient coupling assembly forming substantially the only coupling between the surgical device and the patient, the single patient coupling assembly including the distal ring and the tubular diaphragm. Applicants submit that independent apparatus claim 41 is not obvious in view of the count/claims of Leahy. In other words, it would not have been obvious in view of the Leahy count to use a single patient coupling assembly as claimed as substantially the only coupling between the surgical device and the patient.

None of the claims of Leahy recognize the benefits associated with a surgical device including a single patient coupling assembly as claimed in claim 41. As noted above, the single patient coupling assembly utilizes a distal ring and a tubular diaphragm to secure the surgical device in place. Thus, there is no need for additional

securing structures to assist in coupling the surgical device to the patient. Devices that use additional or alternative securing structures, such as an adhesive similar to that disclosed in Leahy, are cumbersome to use and configured to work against the forces of the insufflation pressure and, therefore, susceptible to separation from the patient. Any partial or full separation of the surgical device from the patient is unacceptable and may result in a loss of insufflation pressure from inside the patient. In addition, the use of an alternative or additional securing structure than that claimed in independent claim 41 may not allow for appropriate use with more than one patient skin thickness. For example, surgical devices having a securing structure including an adhesive for attaching to a patient's skin may include a protection layer of the device extending into the incision having a length that is not equal to the skin thickness of the patient, which could result in the distal end of the protection layer dangling within the patient's body. Such a result would be inconsistent with the goal of protecting the incision from contamination during the surgical procedure.

The simplicity of the claimed device and method and the superior results are not suggested or restricted by Leahy. For at least the above reasons, independent apparatus claim 41 and its dependent claims are not obvious in view of the count of the relevant interference proceedings and the claims of Leahy. For the same reasons, independent claims 25, 72, and 86 and their respective dependent claims are not obvious from the count of the relevant interference proceeding and the claims of Leahy.

Applicants are Entitled to Benefit under 35 U.S.C. § 119(d)

Applicants' claims are entitled to the priority date of at least Irish Patent Application No. 930649, filed September 6, 1993 ("the '649 application"), under 35

U.S.C. § 119(d). The '649 application lists Frank Bonadio and Patrick Leahy as inventors. Patrick Leahy, however, is not listed as an inventor in this application. Rather, the present application lists Frank Bonadio and Alan Reid as inventors. In situations such as this where there is an inconsistency in inventorship between a foreign priority application and a nonprovisional application claiming benefit to the priority application, the PTO suggests that the priority date should be refused until the inconsistency is resolved. See M.P.E.P. § 201.15.

The patent laws of Ireland do not require that the actual inventors be listed initially on an Irish patent application, nor does the inventorship identified initially on an Irish patent application affect the validity of an Irish patent. (See Declaration of Denis McCarthy, Exhibit A). Under Irish patent law, there is a period of 16 months from the filing date of an Irish patent application to provide details of inventorship and derivation of rights. Since the '649 application was only used for priority purposes and was thus abandoned after 12 months, there was no need to conduct an inventorship investigation with respect to the '695 application. Accordingly, an inventorship investigation was not necessary prior to filing the '649 application and any error in the listing of Patrick Leahy as inventors on the '649 application was not legally significant.

Inventorship is resolved by looking to the claims and determining the inventorship for each claims. See 35 U.S.C. 116. The present application includes a claim directed to, *inter alia*, a distal ring, a tubular diaphragm extending proximally from the distal ring, and a single patient coupling assembly forming substantially the only coupling between the surgical device and the patient, the single patient coupling assembly including the distal ring and the tubular diaphragm. Similar features are recited in the remaining

claims of the present application. These features are found in Fig. 9 of both this application and the '649 application. Further, as explained in the attached Declarations of Frank Bonadio and Alan Reid, Frank Bonadio and Alan Reid conceived of these combined claimed features and Patrick Leahy did not. (Exhibits B and C)

Applicants also submit herewith as Exhibit D a final order from an Irish High Court prohibiting Patrick Leahy from representing that he is an inventor of "Dexterity the Amendments and Twist Valve." Dexterity and the Amendments correspond to the subject matter of the '649 application (Exhibit E). This order from the Irish court supports the position that Patrick Leahy is properly omitted as an inventor from the present application.

In view of the above, the inventorship inconsistency between the '649 application and the present application has been satisfactorily explained. Thus, Applicants request that the examiner indicate that Applicants are entitled to the benefit of the priority date of at least the '649 application, and that Leahy is not prior art under 35 U.S.C. § 102(e): Leahy was filed on September 2, 1994, while the present invention should be accorded the benefit of the September 6, 1993, priority filing date of the '649 application.

Miscellaneous Issues

The Office Action contains additional characterizations of the claims and alleged admissions by the Applicants or Applicants' Representative with which Applicants do not necessarily agree. Unless expressly noted otherwise, Applicants decline to subscribe to any statement or characterization in the Office Action.

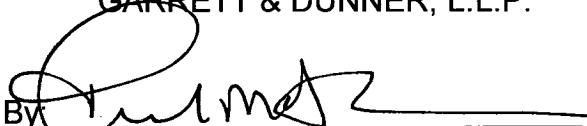
Should the examiner believe that a discussion of this application would expedite resolution of outstanding matters, the examiner is invited to call the undersigned at 202.408.4469.

If there are any other fees due in connection with the filing of this Preliminary Amendment, please charge the fees to Deposit Account No. 06-0916.

Respectfully submitted,

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By 
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